REMARKS

Claims 16-31 were pending in this application when the present Office Action was mailed (February 25, 2005). Claim 16 has been amended and new claims 50-56 have been added. Accordingly, claims 16-31 and 50-56 are currently pending.

In the February 25, 2005 Office Action, claims 16-31 were rejected. More specifically, the status of the application in light of the present Office Action is as follows:

(A) Claims 16-19, 30 and 31 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,725,094 to Saberski ("Saberski");

(B) Claims 20-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Saberski; and

(C) Claims 28 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Saberski in view of U.S. Patent No. 6,463,328 to John et al. ("John").

A. Response to the Section 102 Rejections

Claims 16-19, 30 and 31 were rejected under 35 U.S.C. § 102(e) as being anticipated by Saberski. Claim 16, as amended, is directed to a computer-based method for automatically determining a favorable neuro-stimulation program for a patient. The method includes applying an electrical stimulation to a target therapy site of the central nervous system of the patient (emphasis added). The method further includes, *inter alia*, sensing a response to the applied electrical stimulus and determining whether the response is within a desired range, or an improvement over a previous sensed response from a different electrical stimulus and/or a different configuration of therapy electrodes. The method further includes selecting an alternate configuration of therapy electrodes and/or an alternate electrical stimulus. The method then includes repeating the applying, sensing and determining procedures using the alternate configuration (and/or the alternate electrical stimulus) and choosing a configuration of therapy electrodes (and/or an electrical stimulus) corresponding to a sensed response that is within a desired range and/or provides a better result compared to other sensed responses. Accordingly, methods conducted in accordance with the

features of claim 16 can be used to treat central nervous system disorders using an automated feedback arrangement that adjusts the manner in which stimulation is provided to the central nervous system.

In contrast to claim 16, Saberski is directed to a method for treating labor pain typically associated with uterine contractions. Accordingly, Saberski discloses a sensor structured and positioned to detect a signal indicative of a contraction experienced by the patient. The sensor is coupled to a stimulator structured to apply stimulation to the patient (column 2, lines 1-4). The stimulation is provided to a peripheral site of the patient (see Figure 1), and is provided to reduce labor pain experienced by the patient (column 2, lines 25-26). Feedback provided by the sensors can be used to control the timing and intensity of the electrical stimulation (column 3, lines 45-47).

To anticipate a claim, the prior art reference must disclose each and every element of the claim. Saberski does not anticipate claim 16 for at least the reason that Saberski fails to disclose or suggest applying an electrical stimulus to a target therapy site of the central nervous system of a patient. Instead, Saberski discloses applying stimulation to a peripheral site to control pain. Nor would one of ordinary skill in the art be motivated to modify Saberski's disclosure to either (a) move his stimulation device from its peripheral location to the central nervous system, or (b) move his sensors to a position where they can sense the effects of the stimulus on the central nervous system. In fact, to do so would appear to eliminate the intended effects of Saberski's devices and methods, which are to control labor pain resulting from uterine contractions. Accordingly, the Section 102 rejection of claim 16 should be withdrawn.

Claims 17-19 and 30-31 depend from claim 16. Accordingly, the Section 102 rejections of these claims should be withdrawn for the foregoing reasons and for the additional features of these dependent claims.

B. Response to the Section 103 Rejections on the Basis of Saberski

Claims 20-27 were rejected under Section 103 on the basis of Saberski. In rejecting these claims, the Office Action cites to Mann, presumably U.S. Patent No. 6,622,048 which was applied in an earlier Office Action. The undersigned attorney

assumes that the references to Mann were intended to be references to Saberski, as Mann was not specifically identified as being applied against claims 20-27 in the current Office Action.

With the foregoing assumption in mind, Saberski fails to disclose or suggest the features of claims 20-27, including the time limitations provided by these claims. In some cases, Saberski would appear to teach away from such features. For example, claim 21 includes applying, sensing, determining, selecting, repeating and choosing procedures in a manner that is repeated on the same patient within a period that can extend up to one week. It is unlikely that methods associated with reducing labor pain would be applied for such a period of time. Accordingly, for the reasons discussed above with reference to independent claim 16, and for the additional features of dependent claims 20-27, the Section 103 rejections of these claims should be withdrawn.

C. Response to the Section 103 Rejections on the Basis of Saberski and John

Claims 28 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Saberski and John. Claims 28 and 29 both depend from claim 16. Claim 28 includes, in addition to the features of claim 16, attaching EMG sensors to a sense site of the patient, detecting peripheral responses to the stimuli applied to the electrodes, and automatically sending the detected peripheral responses to the controller. Claim 29 includes, in addition to the features of claim 16, using a functional MRI to detect data related to neural activity, and sending the data to a controller.

Assuming for the sake of argument that John discloses the features of claims 28 and 29 that are not disclosed by Saberski, a *prima facie* case of obviousness must further provide the motivation to combine the teachings of John with those of Saberski. As discussed above, Saberski is directed to peripheral stimulation methods for relieving labor pain resulting from uterine contractions. John is directed to brain stimulation methods that are applied to deep brain tissue (see for example repeated references to deep brain stimulation (DBS) at column 3, line 61; column 5, line 43; column 11, line 16; column 17, line 45; and column 22, lines 20-24). It does not appear that anything in

Saberski's disclosure of peripheral stimulation for pain control would lead one of ordinary skill in the art, seeking guidance for sensing or detecting neural activity, to look to John's disclosure of deep brain stimulation techniques. Accordingly, the Section 103 rejections of claims 28 and 29 should be withdrawn.

D. New Claims 50-56

New claims 50-52 depend from claim 16 and include, in addition to the features of claim 16, application of an electrical stimulus at a sub-threshold level (claims 50 and 51) and the application of an electrical stimulus to the cortex (claim 52). New claim 53 includes features of both claims 16 and 17. In particular, new claim 53 includes determining whether a response by a patient is within a desired range or an improvement over a previous sensed response from a different configuration of therapy electrodes. Claim 53 further includes selecting an alternate configuration of therapy electrodes by correlating a plurality of sensed responses with corresponding electrode configurations and estimating a new electrode configuration that is expected to improve the efficacy according to the electrode-configuration/response trend. Neither Saberski nor John appear to disclose or suggest using such a feedback system to control the configuration of electrodes to which an electrical stimulus is applied. Saberski, in a passage cited by the Examiner, discloses at column 4, lines 29-32 a device that can "learn" the patient level preferences and adjust automatically for the next cycle. However, learning patient level preferences does not begin to disclose or suggest changing an electrode configuration (for example, by changing which of a plurality of electrodes are active). Accordingly, claim 53 is patentable over the applied references.

Claims 54-56 depend from claim 53. Accordingly, these claims are patentable over the applied references for the reasons discussed above and for the additional features of this claim.

E. Conclusion

In view of the foregoing, the pending claims comply with 35 U.S.C. § 112 and are patentable over the cited art. The applicant accordingly requests reconsideration of the application and a Notice of Allowance. If the Examiner has any questions or believes a

telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (206) 359-3257.

Respectfully submitted,
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